K090677

Page 1 of 1

510(k) SUMMARY

510(K) NUMBER:	K090677
	MAY - 7 2009
SUBMITTED BY:	Innovia LLC 12415 SW 136 Avenue Unit 3 Miami, FL 33186 305-378-2651
CONTACT PERSON:	Bruce Weber Vice President, Clinical, Regulatory and Quality Assurance
DATE OF PREPARATION:	May 6, 2009
NAME OF DEVICE:	Laparoscopic Access Port
CLASSIFICATION:	Laparoscope, General & Plastic Surgery (21CFR 876.1500)
TRADE NAME:	InnoPort™ Laparoscopic Access Port
PREDICATE DEVICE:	Advanced Surgical Concepts TriPort Laparoscopic Access Device (K073719) Ethicon Endopath Blunt Tip Trocar (K032676)

INTENDED USE: The InnoPort™ Laparoscopic Access Port is a sterile, single use device, intended for use as a multiple instrument and/or camera port during minimally invasive laparoscopic abdominal surgery.

DEVICE DESCRIPTION: The InnoPort™ Laparoscopic Access Port is a sterile, single use laparoscopic access device made of a flexible Quatromer polymer combined with polycarbonate and polyurethane components. It forms a truncated cone approximately 5.0 centimeters long (not including instrument ports), with three individual laparoscopic instrument ports at the larger end. A fourth port connects to the insufflation system to provide intra-abdominal pneumoperitoneum. The instrument ports are designed to accommodate 5 mm diameter laparoscopic instruments while allowing full maneuverability without loss of pneumoperitoneum. The complete device is designed to be inserted through a single incision into the abdominal cavity for the duration of surgery.

PERFORMANCE DATA SUMMARY: The performance and functional testing of the InnoPort™ Laparoscopic Access Port included bench and *in vivo* tests to verify its ability to maintain pneumoperitoneum with minimal leakage, allow introduction and manipulation of instruments, and meet performance specifications. The testing demonstrated that the InnoPort™ Laparoscopic Access Port is substantially equivalent to its predicate device and it introduces no new safety or effectiveness issues when used as instructed.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 7 2009

Innovia LLC
% Mr. Bruce Weber
VP, Clinical, Regulatory and QA
12415 SW 136 Avenue, Unit 3
Miami, Florida 33186

Re: K090677
Trade/Device Name: Innovia InnoPort™ Laparoscopic Access Port
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ
Dated: June 30, 2009
Received: June 30, 2009

Dear Mr. Weber:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at (240) 276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Mark N. Melkerson
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K090677

Indications for Use

510(k) Number: K090677

Device Name: Innovia InnoPort™ Laparoscopic Access Port

Indications for Use:

The Innovia InnoPort™ Laparoscopic Access Device is a sterile, single use device intended for use as a multiple instrument and/or camera port during minimally invasive laparoscopic abdominal surgery.

Prescription Use __X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE –CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. Ogden for

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K090677